SUPPORT FOR THE AMENDMENTS

Newly added Claims 21-28 are supported by the specification at pages 2-17 and by original Claims 1-20. No new matter is believed to have been added to this application by these amendments.

REMARKS

Claims 21-28 are pending. Favorable reconsideration is respectfully requested.

The present invention relates to a mouse suitable as a model for an allergic disorder, wherein the mouse is a NC/Nga mouse which has been impregnated with an extract of an antigen selected from a specified group, under a specific pathogen free environment such that the animal displays allergy symptoms caused by the antigen. See Claim 21.

The present invention also relates to a method of producing the mouse by maintaining a NC/Nga mouse in a Specific Pathogen Free environment and impregnating the animal with the extract of the antigen. See Claim 25.

The rejection of the claims under 35 U.S.C. §102(b) over Morita et al. is believed to be obviated by the amendment submitted above. Claim 21 recites a NC/Nga mouse which has been impregnated with an extract of an antigen selected from a specified group. As recognized by the Examiner, Morita et al. fail to describe administering an extract of an antigen to the mice (see the Official Action dated October 2, 2001 at page 11). Accordingly, the reference fails to describe the claimed mouse, and withdrawal of this ground of rejection is respectfully requested.

The rejection of Claims 1 and 12 under 35 U.S.C. §103(a) over Morita et al. in view of Yasue et al. is respectfully traversed. These references fail to suggest the claimed mouse.

As discussed above, Morita et al. fail to describe administering an extract of an antigen to the mice. In addition, Morita et al. did not use the specific pathogen free (SPF) condition. The condition used by Morita et al. is used is not a SPF condition since live mites were used. Moreover, Morita et al. have not eliminated environmental factors other than mite allergen. Skin diseases associated with mite infection can be considered to be initiated by the stimulus to which the mites bite the skin. Moreover, under the conventional environment accompanying mite infection, it is difficult to check whether or not mite allergen causes the skin lesion.

Yasue et al. describe the inhibition of airway inflammation in rDer f 2-sensitized mice by oral administration of recombinant Der f 2 (see the abstract). This reference describes challenging mice with a crude mite extract (page 30, column 2).

The Examiner has provided no evidence that one of ordinary skill in the art would be motivated to substitute mite extract for live mites. Several advantages are asserted in the Official Action dated October 2, 2001 in support of such an argument, but no evidence to support those assertions has been provided. Accordingly, the Office has failed to establish a prima facie case of obviousness.

Moreover, the claimed mouse has several advantages as compared to the mouse described by Morita et al.

(1) The claimed mouse can be used in a screening directory. When live mites are used , it is necessary to remove the mites and their eggs by using, for example, acaricide (e.g., ivermectine; see page 38 of Morita et al.)

(2) The claimed mouse eliminates all environmental factors other than mite allergen.

(3) The claimed mouse is readily prepared and has a wide range of applications. Thus, in order to prepare a mouse model for atopic dermatitis, what was necessary was just to inject the suitable skin of the mouse with an extract of the allergen. If one injects the ear of the mouse with the extract, it is very easy to use the screening because the effect of the drug can be assessed quantitatively by measuring the sickness of the ear. Moreover, if one needs the mouse model for a conjunctive allergy, one may administer eye drops containing the extracts.

Based on the foregoing, the claimed mouse is not suggested by Morita et al. in view of Yasue et al. Accordingly, Claims 1 and 12 are not obvious over these references. Withdrawal of this ground of rejection is respectfully requested.

The rejection of Claims 15-16 and 18-19 under 35 U.S.C. §103(a) over Morita et al. in view of Hiroi et al. is respectfully traversed. At page 12 of the Official Action, only Hiroi et al. cited in combination with Morita et al. However, at page 13 of the Action Yasue et al. is discussed. Therefore, the rejection will be addressed as if the cited combination of references was Morita et al. in view of Hiroi et al and Yasue et al. These references fail to suggest the claimed method of screening.

Hiroi et al. describe the effect of FK506 ointment on spontaneous dermatitis in NC/Nga mice (see the abstract). This reference was cited to support an argument that it (allegedly) provides motivation for testing potential therapeutic agents in mouse models of atopic dermatitis. However, this reference does not remedy the deficiencies of the combination of Morita et al. and Yasue et al. discussed above.

Based on the foregoing, the claimed mouse is not suggested by Morita et al. in view of Hiroi et al. and Yasue et al. Accordingly, Claims 15-16 and 18-19 are not obvious over these references. Withdrawal of this ground of rejection is respectfully requested.

Applicants respectfully submit that the rejection of the claims under 35 U.S.C. §112, first paragraph, is obviated by the amendment submitted above. Claim 21 recites, *inter alia*, a NC/Nga mouse which has been impregnated with an extract of an antigen selected from a specified group. The specification provides a detailed description of how to make and use the mouse as claimed. Therefore, the claimed mouse can be prepared without undue experimentation. Accordingly, the claims are enabled. Withdrawal of this ground of rejection is respectfully requested.

Applicants respectfully submit that the rejection of the claims under 35 U.S.C. §112, second paragraph, is obviated by the amendment submitted above. Newly-added Claims 21-[] do not recite the term "immuno-modulated." Accordingly, withdrawal of this ground of rejection is respectfully requested.

The Restriction Requirement is now moot, since the non-elected claims have been canceled.

Applicants submit that the present application is in condition for allowance. Early notice to this effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

Norman F. Oblon
Attorney of Record
Registration No. 24,618

James J. Kelly, Ph.D.
Registration No. 41,504

22850
Tel. (703) 413-3000
Fax. (703) 413-2220
(OSMMN 11/98)

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IN THE CLAIMS

Claims 1-20 (Canceled)

Claims 21-28 (New)